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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,402

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V. Suzanne Klimberg

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,402

Applicant(s)

KLIMBERG ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,8-14 and 44-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 10-12 is/are allowed.
- 6) ☒ Claim(s) 6,9,13,14 and 44-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-21-06</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 6, 8-14 and 44-56 are presented for examination.

Applicants' amendment and information disclosure statement filed February 21, 2006 have been received and entered.

Accordingly, the rejection made under 35 USC 102 as set forth in the previous Office action dated November 14, 2005 at pages 5-6 is hereby withdrawn because the applicants amended claim 6 to added a carbohydrate.

Allowable Subject Matter

Claims 8 and 10-12 are allowable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 9, 13, 14, 44-47 and 52-56 are again provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

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claims 10-12 of copending Application No. 10/903,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the present claims and the copending claims lies in that the present claims, an additional ingredient, a carbohydrate is administered with the presently claimed active agent.

The present claims would anticipate the copending claims because the copending claims recite "comprising" and thus opens the claims to the inclusion of additional active ingredients.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 6, 9, 13, 14, 44-47 and 52-56 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 9, 13, 14, 44-47 and 52-56 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting breast tissue against damage from radiation therapy, comprising administering to a mammalian subject afflicted with breast cancer a composition comprising glutamine and a carbohydrate, does not reasonably provide enablement for protection non-mucosal tissue against damage from radiation therapy wherein in subject is afflicted with other types of cancer such as skin cancer. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

Again, applicants' remarks regarding the rejection made under 35 USC 112, first paragraph is improper and moot by the incorporation of claim 7 are not persuasive since the applicants' scope of enablement is enabled for protection non-mucosal tissue (breast tissue) wherein the subject matter is afflicted with breast

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cancer. Again, applicants' specification only shows working examples limited to treating breast cancer and not other types of cancer such as skin cancer which contains non-mucosal tissue.

The rejection made under 35 USC 112, first paragraph is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 9, 13, 14 and 44-56 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilmore (5,248,697) of PTO-1449 in view of Pellico (5,817,695).

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Wilmore teaches the administration of glutamine to a mammal to reduce or prevent radiation-associated oxidative damage in the tissues that would include non-mucosal tissue such as breast tissue (See the abstract). Note particularly, column 7, lines 66-68 to column 8, lines 1-3; states the glutamine administration reduce the toxicity associated with chemotherapeutic agents for the treatment of carcinoma of the colon, rectum, breast, stomach and pancreas, Note particularly, column 8, lines 6-8 states the glutamine administration can be continued during the chemotherapy (same as applicants' claim 56).

The instant invention differs from the cited reference in that the cited reference does not teach the addition of a carbohydrate. However, the secondary reference, Pellico, teaches a nutritional product that is provided to cancer patients, including breast cancer patients, comprising a carbohydrate and amino acids including glutamine. Note the reference teaches the composition comprising no more than 5 naturally occurring amino acids other than glutamine (see column 14, claim 9). Clearly, the secondary reference, Pellico, teaches a composition comprising glutamine and a carbohydrate administered to cancer patients to help suppress cancer growth and adjunct to conventional cancer therapies such as radiation is old and well-known in the art (see the abstract). The applicants have not provide any unexpected results or experimental data showing the combination of the two components, glutamine and a carbohydrate for protection non-mucosal tissue against damage from radiation therapy (conventional cancer therapies).

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The instant invention differs from the cited references in that the cited references do not teach the preferred amount of glutamine administered to the subject as disclosed in claims 44-47, 50 and 51. However, to determine an amount having optimum effectiveness to protect non-mucosal tissues against damage from radiation therapy is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum amounts to get the maximum effectiveness in the absence of evidence to the contrary.

Claims 6, 9, 13, 14 and 44-56 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:00 am-8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
May 10, 2006